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09/254,563	03/05/1999	VICTOR BRONSHTEIN	UPTINC.015A	7197

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EXAMINER
SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	13

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/254,563	Bronshtein
Examiner	**Art Unit**
Sandra Saucier	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 22, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 4-10, 12-16, 25, and 26 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 4-10, 12-16, 25, and 26 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1, 4-10, 12-16, 25 and 26 are pending and are considered on the merits.

Claim Rejections - 35 USC § 112

INDEFINITE

Claim 1, 4-10, 12-16, 25 and 26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "vitrifying the dehydrated specimen by cooling to a refrigeration or higher storage temperature.".

It is uncertain just what temperature constitutes "a refrigeration temperature". It cannot be determined what exact temperature is the lower limit of the phrase "a refrigeration temperature", because refrigeration is defined by Gould's Medical Dictionary to be "The act of lowering the temperature of a body by conducting away its heat to a surrounding cooler substance"; therefore, a refrigeration temperature is interpreted to be any temperature where heat is conducted away from a body. The upper limit of this phrase "or higher" cannot be clearly understood, as it may mean that no lowering of the temperature of the initial temperature of the specimen takes place. It is not possible that vitrification takes place without cooling or lowering of the initial temperature of the specimen. Thus, this phrase is not interpretable.

Applicant argues that the common meaning of the word "refrigeration" is meant and supplies a definition from Webster's II New Riverside Dictionary where one of the definitions is "To chill a substance in a refrigerator". The applicant has then attempted to explain that "a refrigeration temperature" is that achieved by a refrigerator. To support this interpretation, applicant has submitted a portion of a sales catalog showing outdoor walk-in type cold storage apparatus with a holding range of from -34°C to 27°C as attachment A. Applicant has also submitted in attachment B, a catalog page from Weiss Instruments showing thermostats, refrigerators and freezers which have a range of -55°C to 120°C. However, these ranges are not the same range, that is the range of -34 to 27°C from attachment A is not the same range as -55 to 120°C which is the range in attachment B. Even the term, "refrigerator", or "the temperature achieved by a refrigerator", is one which has no metes and bounds as clearly demonstrated by

applicant's own submission.

Further, one may argue on the one hand, that a temperature achieved by a refrigerator is a little above freezing, else the apparatus may be called a 'freezer'. Thus, applicant has urged that the temperature achieved by freezers fall within his newly defined temperature limitations of "refrigeration temperature".

This also clearly demonstrates the confusion surrounding this imprecise temperature limitation.

On the other hand, since freezers are urged by applicant to be included as "refrigerators", please see the appended Schoeller Instruments Catalog (exhibit 1) available on the Internet, where mechanical freezers can achieve temperatures of -152°C. Non mechanical refrigerators may achieve temperatures near absolute zero (0°K or -273°C), such as the Kelvinox MX dilution refrigerator, appended as exhibit 2.

However, the term in question here is not "refrigerator", but "refrigeration temperature". First, Gould's Medical Dictionary defines "refrigeration" to be "The act of lowering the temperature of a body by conducting away its heat to a surrounding cooler substance"; therefore, a refrigeration temperature is any temperature where heat is conducted away from a body. Second, Grant & Hackh's Chemical Dictionary defines "refrigeration" as "The production of cold; the lowering of the temperature of a body by conducting away its heat." Appendix 3. Thus, two dictionaries, which are scientific dictionaries and used by those of skill in the sciences, have no temperature limitations associated with the word "refrigeration".

Further, the term "refrigeration" has no definite temperature limitations according to the Handbook from the Chemistry Department of Ohio State by Eric Spencer, accessible on the Internet, Appendix 4. Please see the discussion concerning two interpretations of the temperature limitations of the term "refrigeration", which is appended. One interpretation used by those of skill in the art is a temperature range down to -73.3°C. Another interpretation used by those of skill in the art is a temperature range down to a few degrees of absolute zero, which is -273°C.

Even Webster's New World Dictionary, College Edition, which may be

argued to be yet another common, everyday interpretation of "refrigeration", defines this term as 1 "to make or keep cool or cold; chill, 2 to preserve (food biologicals, etc.) by keeping cold or freezing (Appendix 5). Note that there are no temperature limitations associated with even this common, non-scientific definition.

Thus, the cited evidence clearly points to the lack of definite limits for the term "refrigeration temperature", the specification is without definition and the specification lacks an exemplification of a "refrigeration temperature". As the metes and bounds of "refrigeration temperature" cannot be determined, the claims are still held to be indefinite.

Claim 1 is unclear because it appears that it is intended that a cooling or lowering of the temperature occurs, but no mention of the starting temperature is present in the claim; therefore, one cannot determine what cooling means because there is no starting temperature or step from which to measure. "Cooling" is a relative term with no reference point.

Claim 12 is indefinite because there is no permeating rehydration cryoprotectant in the rehydration solution. Thus, the decreasing of the chemical potential of a permeating rehydration cryoprotectant makes no sense unless a permeating rehydration cryoprotectant is present.

NEW MATTER

Claims 1, 4-10, 12-16, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In the "Summary of the Invention", no step of vitrifying the specimen is seen. Rather, the invention is directed solely to the contacting of the specimen with solutions termed "vitrification solutions" or "rehydration solutions". In the "Detailed Description of the Preferred Embodiments", the preservation method described consists only of contacting the specimen with various solutions. No mention of vitrifying the specimen is seen. Please point to the passage where the vitrifying step is found.

This is a matter of written description, not a question of what one of skill

in the art would or would not have known. Applicant must limit claims to the material within the four corners of the as-filed specification. If the material is not present, the material is new matter.

Also, the newly submitted abstract also inserts a vitrifying step.

Claim Rejections - 35 USC § 102

Claims 1, 4-7, 16, 25 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Titterington *et al.* [U].

The claims are directed to a method of preserving cells or tissue by equilibrating and dehydrating a cell or tissue with a solution comprising a

1) non-permeating co-solute (amino acids or derivatives, betaine, carbohydrate such as {aldose monosaccharide, ketose monosaccharide, amino sugar, alditol, inositol, aidonic, uronic or aldaric acid}, a sugar alcohol, disaccharide or polysaccharide),

2) a permeating cryoprotectant (DMSO, ethylene glycol, propylene glycol or glycerol) and

3) a non-permeating polymeric cryoprotectant (dextran, starch, PEG, PVP, Ficoll, peptides),

vitrifying the specimen by cooling to a refrigeration or higher storage temperature.

Titterington *et al.* disclose a method of cryopreservation of mouse embryos comprising treating the embryos with a composition containing 1) sucrose (0.75M), 2) 50% glycerol and 3) 50% Percoll and cooling ultimately to the temperature of liquid nitrogen. The embryos are in a vitrified state.

Since refrigeration is defined by Gould's Medical Dictionary to be "The act of lowering the temperature of a body by conducting away its heat to a surrounding cooler substance" and also by Grant and Hack's Chemical Dictionary to be "The production of cold; lowering of the temperature of a body by conducting away its heat.", the act of placing embryos in liquid nitrogen, which is a surrounding cooler substance which conducts heat away from the embryos, is

considered to be the act of refrigeration and is therefore reducing the temperature of the specimen to "a refrigeration temperature" and, thus, to fulfill the claim limitations.

Claims 1-6, 9, 10, 16, 18-24, 25 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rall *et al.* [V].

Rall *et al.* disclose a method for cryopreserving embryos comprising treating the embryos with a composition comprising 1) glucose, 2) glycerol 6.5M, 3) BSA. The concentration of the components of the solution is increased stepwise (page 682). The embryos are vitrified by cooling ultimately to -196C.

See foregoing discussion regarding "refrigeration, refrigeration temperature, refrigerators".

Claims 1, 4-7, 9, 12-16, 25 and 26 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,364,756 [D].

US 5,364,756 disclose a method of preserving cells (col. 4, l. 60) by contacting the cells with a solution comprising 1)raffinose, 2) DMSO and 3) dextran (col. 13, tables). The sample is dried using the temperature program in col. 17, l. 32-46. The sample is stored and rehydrated with a solution containing 1) DMSO, 2) trehalose, 3) dextran, col. 20, table. The rehydration solution is then diluted with culture medium.

In example 4, the red cell sample is contacted with 1% glycerol, suspended in 1% dextran, treated with a vitrification solution, VS1, 0.025M DMSO, 0.025M propylene glycol, 0.0125M butanediol, 0.5% raffinose, 0.3% trehalose, 0.3% sucrose, 0.6% PVP, 0.6% dextran, nebulized, and the temperature of the nebulized sample is ultimately brought down to -190C. The samples were then dried by molecular distillation and stored under vacuum. In col. 14 is described that the most preferred procedure for cooling is a vitrification procedure. Thus, it is reasonable to assume that in the examples, the most preferred procedure is exemplified.

Applicant states that the claimed method is drawn to vitrification under refrigeration temperatures. Although the term "refrigeration temperature" is indefinite, for the sake of argument, it will arbitrarily be assumed that such a

temperature includes -152°C, which is a temperature achieved by a mechanical refrigerator as shown in the Schoeller Instruments Catalog and as urged as a definition by applicant.

The temperature at which the specimen vitrifies in the cited prior art will be below the T_g of the specimen which includes the vitrification solution. The T_g of the vitrification solution and sample is thought to be about -100 to -130°C (col. 15, l. 44) and a closed circuit refrigeration system may be used to maintain the sample temperature below the (glass) transition temperature. Thus, the cited prior art teaches the use of a refrigeration temperature to achieve the glass or vitreous state.

Further, the dehydrated specimen in Example 4 was stored under vacuum for up to 2 weeks (col. 22, l. 48), presumably at 4°C as taught in Example 2 (col. 21, l. 9) or Example 3.

Also, applicant's claim is not closed to further manipulation of the specimen including freeze drying, but merely requires that the sample reach the state of vitrification at refrigeration temperature or higher. The vitrification temperature of the sample is determined solely by the kind and concentration of the cryoprotectants present in the sample. The kind and concentration of cryoprotectants is the same as in applicant's claimed method. Thus, the temperature at which the sample vitrifies in the prior art is reasonably considered to be the same as in the claimed method.

Claims 1, 4-7, 9, 10, 12-16, 25 and 26 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5,800,978 [E].

US 5800978 discloses a cryopreservation medium comprising 0.5M glycerol, 7.5% BSA and 0.3M glucose or 5% glucose, 10% FCS, 20% Dextran 40 (Table 1). A method of cryopreservation or red cells using 5% glucose (permeant), 10% sucrose (impermeant) and 20% PVP (impermeant) (buffer #8 Table 2) and other three component combinations of cryoprotectants is shown. The general principle of using a three component cryoprotectant buffer comprising a permeant (monosaccharides or polyalcohols), impermeant (disaccharide) and a high molecular weight polymer is disclosed in Example 1. Example 1 also states that the Tg of the solution MUST BE ADJUSTED to that the Tg exceeds -45C and preferably is above -25C for convenient frozen storage.

In example 4, 5.7 mls of cryoprotectant buffer was added to 5 mls of cells in dextrose-saline then an additional 5.7 mls of buffer was added prior to lowering the temperature to -80C. This is a one step increase in concentration of the buffer prior to lowering the temperature. During thawing, the cells were reconstituted by dilution of the freezing buffer with a reconstitution buffer comprising PVP and glucose (example 4). In table 11, red cells after dehydration are stored at 80°C for 4-6 days. In Table 10, a mixture of glycerol, glucose, lactose and HES is added to red cells prior to lyophilization.

Applicant argues that the reference discloses "freezing" not vitrification. However, the reference discloses quickly lowering the temperature of the sample to -80C which is below the Tg of the cryoprotectant about -30C. Therefore, the sample is vitrified because the temperature has been lowered below the temperature at which it vitrifies (glass transition temperature, T_g). Whether of not the reference appreciates that the sample is not "frozen" or has used improper language to describe a state which results from the performance of the disclosed steps is of little import. Lowering the temperature of a vitrifiable mixture below its vitrification point results in a vitrified sample whether or not the true state of the sample is appreciated or conveyed in the text.

Applicant argues that the instant invention does not disclose vitrification, but discloses a method "that at appropriate temperatures form partially crystalline mixtures of water ice with interspersed regions of a separate amorphous glass phase". However, since the physical steps disclosed in the prior art are the same physical steps that are performed in the claimed method and use the same permeant and impermeant cryoprotectants in the same concentrations to achieve glass transition points of the specimen which are above the temperatures to which the specimens are cooled, and as vitrification is a result of the lowering of the temperature of the specimen below the glass transition temperature, the results of the method disclosed in the prior art are reasonably assumed to be the same as the results that are in the pending claims. Whether applicant or cited prior art achieves the state of matter that they anticipate or claim has not been demonstrated.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim

limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re* King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the

reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the vitrification of the sample flows from the use of a vitrifiable solution containing the sample with a glass transition temperature which is higher than the storage temperature. Thus applicant is incorrect in arguing that the anticipatory rejection is improper.

Applicant also argues that '978 teaches away from the use of DMSO. The reason that '978 teaches away from the use of DMSO is that '978 is particularly concerned with the storage of platelets and DMSO is not FDA approved for such use (col. 2, l. 4). The reference does not generally teach that DMSO should be avoided for all cells or tissues or that DMSO does not function as a cryoprotectant. Further, applicant's claims do not require DMSO as a critical component of the cryoprotectant solution.

Applicant argues that '978 does not teach "a non-permeating co-solute". However, '978 teaches the use of a multi-component solution such as glycerol (permeant), HES (non-permeant) and lactose (a non-permeating co-solute). The specification on page 11 states that "disaccharides (sucrose, trehalose, etc.)" are non-permeating co-solutes (page 11, line 34). Therefore, the argument is without merit.

Applicant further argues that glucose is not taught as a permeant component and is not one of the compounds listed in claim 4. However, Table 10 of the prior art teaches the use of the use of a solution comprising glycerol which is one of applicant's claimed permeants.

Claim Rejections - 35 USC § 103

Claims 1, 4-10, 12-16, 25 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5364756 [D] in view of US 5,217,860 [C] taken with US 4,865,871 [E] or Rall *et al.* [V] and US 5,879,876 [F].

The claims are directed to a method of preserving cells or tissue by equilibrating and dehydrating the cell or tissue with a solution comprising a 1) non-permeating co-solute (amino acids or derivatives, betaine, carbohydrate such as {aldose monosaccharide, ketose monosaccharide, amino sugar, alditol, inositol, aidonic, uronic or aldaric acid}, a sugar alcohol, disaccharide or

polysaccharide), 2) a permeating cryoprotectant (DMSO, ethylene glycol, propylene glycol or glycerol) and 3) a non-permeating cryoprotectant (dextran, starch, PEG, PVP, Ficoll, peptides), vitrifying the sample, without freezing by cooling to a refrigeration temperature of higher. Dependent claims require an increase in the concentration of the cryopreservative solution or a decrease in the concentration of the rehydration solution.

The primary reference of US 5,364,756 lacks the use of increasing concentrations of cryoprotectant prior to freezing.

US 5,217,860 disclose a method of cryopreserving tissue comprising adding a solution containing 1) formamide, 2) DMSO and increasing the concentration of the solution according to a desired profile.

US 4,865,871 discloses the details of the protocol used in US 5,364,756 (col. 11, l. 1-18).

US 5,879,876 discloses a general method of diluting a cryoprotectant from a thawed tissue using Plasmalyte and mannitol (ex. 2). Plasmalyte contains glucose which is a permeant.

The other references are relied upon as explained above.

The use of an increasing concentration of cryopreservatives prior to cooling the temperature of a sample in the place of the one step addition method as disclosed by US 5364756 would have been obvious when taken with US 5217860 or Rall *et al.* which disclose stepwise increases in the concentration of cryoprotectants prior to cooling in order to decrease osmotic stress in cells/tissues. The stability of the processed tissue as disclose by US 5364756 is assume to be the same as the claimed stability because the process which produces the stable product, as claimed, is essentially the same as the process disclosed in the prior art. In particular, see US 4865871 which discloses a method of sublimation and storage of biological samples after the addition of cryoprotectants. US 5364756 also discloses diluting the cryoprotectant solution after reconstitution (col. 20, table). US 5879876 discloses that gradual dilution of the cryoprotectant after thawing lessens osmotic shock of the tissue.

The method of increasing concentrations of cryoprotectants prior to

freezing and decreasing concentrations of rehydration solutions during reconstitution or thawing is well known in the art. The cryoprotectant compositions as well as the rehydration compositions are also well known in the art. Neither the claimed method nor the claimed compositions are allowed.

One of skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Applicant argues that none of the references suggest vitrifying a dehydrated specimen by cooling to a refrigeration or higher storage temperature. However, the indefiniteness of this temperature range permits the interpretation given above to the scope of the claim.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 6:00 PM Monday and Tuesday and 8:30 AM-12:30 PM on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

Sandra Saucier
Primary Examiner
Art Unit 1651
April 5, 2002